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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,020	02/02/2005	Atsushi Ozaki	05273.0095-00000	7467

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EXAMINER	
HENLEY III, RAYMOND J	
ART UNIT	PAPER NUMBER
1614	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/523,020	OZAKI ET AL.	
	Examiner	Art Unit	
	Raymond J. Henley III	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/6/05, 4/14/06 & 7/19/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

CLAIMS 1-19 ARE PRESENTED FOR EXAMINATION

Applicants' Preliminary Amendments filed February 2, 2005 and March 8, 2005 and Information Disclosure Statements filed June 6, 2005, April 14, 2006 and July 19, 2006 have been received and entered into the application. Accordingly, the specification at pages 1, 4 and 20 has been amended. Also, as reflected by the attached, completed copies of form PTO/SB/08, (5 sheets total), the Examiner has considered the cited references.

Claim Rejection - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 16-19 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejection - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 and 9-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

"The primary purpose of this requirement of definiteness of claim language is to ensure that the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent. A secondary purpose is to provide a clear measure of what applicants regard as the invention so that it can be determined whether the claimed invention meets all the criteria for patentability and whether the specification meets the criteria of 35 U.S.C. 112, first paragraph with respect to the claimed invention.", (see MPEP § 2173).

The term "severe" in the expression "severe heart failure" is a relative term which renders claims 1-7 and 9-19 indefinite. In particular, "severe" does not particularly point out a tangible degree of heart failure intended by Applicants that would be immediately recognized by the skilled artisan. Also, Applicants have failed to provide a specific definition for this term in the present specification such that the artisan would be informed of whether or not he/she is infringing the presently claimed subject matter in treating a particular patient suffering from heart failure. The description of severe heart failure at page 12 of the specification is noted, but is not seen to be reasonably clear, precise or deliberate, (see MPEP § 2111), such that the metes and bounds of the expression "severe heart failure" would be clear to the skilled artisan. In particular, at page 12 of the specification, line 3, the exemplary language "for example" indicates that other, non-specified criteria of heart failure may be present such that the heart failure is considered "severe". Lacking notice, however, of what other intended, but non-disclosed criteria may be present in order for the heart failure to be considered "severe", the skilled artisan would not be reasonably apprised of the metes and bounds of the subject matter for which Applicants seek patent protection. Rather, a subjective interpretation of the claimed language would be

required which is inconsistent with the tenor and express language of 35 U.S.C. § 112, second paragraph.

Further respecting claims 16-19, the term "use" does not set forth any steps involved in the method/process and thus it is unclear what method/process Applicants are intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Multiple Reference 35 U.S.C. § 102 Rejections

This Office action contains a rejection under 35 U.S.C. § 102 based on multiple references. The additional reference is relied on to explain the meaning of a term used in the primary reference or to show that a characteristic not disclosed in the primary reference is inherent. Accordingly, the Examiner's reliance on multiple references is proper. "Normally, only one reference should be used in making a rejection under 35 U.S.C. § 102. However, a 35 U.S.C. § 102 rejection over multiple references has been held to be proper when the extra references are cited to:

(A) Prove the primary reference contains an "enabled disclosure;"

(B) Explain the meaning of a term used in the primary reference; or

(C) Show that a characteristic not disclosed in the reference is inherent." (See MPEP § 2131.01).

Claim Rejection - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Ogawa et al., (U.S. Patent No. 5,753,677, cited by Applicants) who teach pharmaceutical compositions, and methods for their preparation, which comprise, as evidenced by Applicants' disclosure at page 2, line 16, the claimed designated benzazepine compounds. Ogawa et al. further teach the claimed compounds in the claimed designated proportions, (see col. 95, lines 46-50).

The statements of intended use in the present claims, i.e., for the treatment of severe heart failure, which statements are not found in Ogawa et al., are noted, but fail to impart patentability to the claimed compositions or processes of producing such compositions because they do not represent any physical feature not found in the prior art compositions.

Claim Rejection - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogawa et al, for the reasons set forth above which are here incorporated by reference, in view of Gheorghiade et al., (abstract cited by Applicants in their April 14, 2006 IDS) and Sorbera et al., ("Tolvaptan", Drugs of the Future reference).

The difference between the above and the claimed subject matter lies in that Ogawa et al. fail to teach that the benzazepine compositions are useful in the treatment of severe heart failure of the type presently claimed.

However, the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains because from Gheorghiade et al., one of ordinary skill in the art would have known that a benzazepine compound, i.e., Tolvaptan, which is representative of those compounds disclosed by Ogawa et al., i.e., see the structure of Tolvaptan in Sorbera et al., was known to be effective in the treatment of heart failure, such as that categorized as New York Heart Association ("NYHA"), Class I-III, when administered in dosages of 30 mg, 45 mg and 60 mg (see the entire abstract of Gheorghiade et al.).

Also, while none of the references disclose the treatment of "severe" heart failure or a heart failure of NYHA class "III and IV", (see present claim 8), the effective therapeutic activity reported by Gheorghiade et al., i.e., reduction of edema and increase in urine output, and disclosed by Ogawa et al., i.e., diuresis, (abstract), would have at least imbued the artisan with a reasonable expectation that the compounds could be similarly, successfully employed in patients suffering from all types of congestive heart failure, including the type that one may subjectively consider as being "severe" or objectively as NYHA class III-IV.

Accordingly, the claims are deemed properly rejected.

None of the claims are currently in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Raymond J Henley III
Primary Examiner
Art Unit 1614

February 15, 2007